

SYSTEMATIC LITERATURE REVIEW ON MULTI-INDICATION PRICING MODELS IN ONCOLOGICAL DRUGS

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BACKGROUND & OBJECTIVES

- In recent years, an increasing number of oncological drugs have been approved for multiple indications. Their clinical value, however, varies across indications, while price is typically uniform. In 2014, 55% of oncological drugs had multiple indications and this ratio is expected to grow to 76% in 2020.

Fig. 1: Clinical value by indication

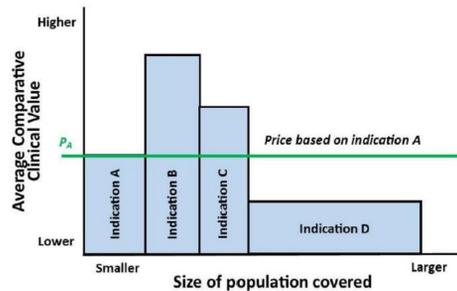
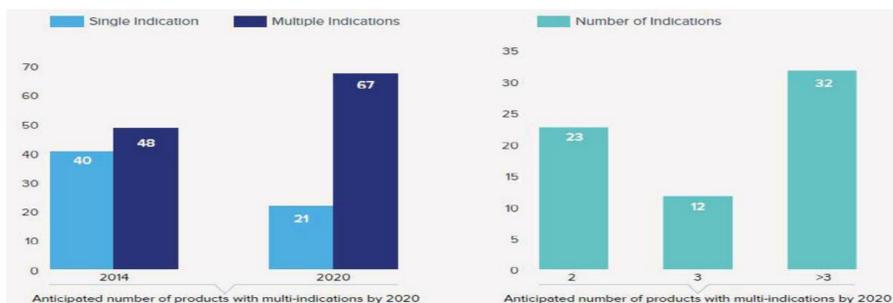


Fig. 2: Multi-indication oncological drugs in 2014 and 2020 (estimated) and number of indications



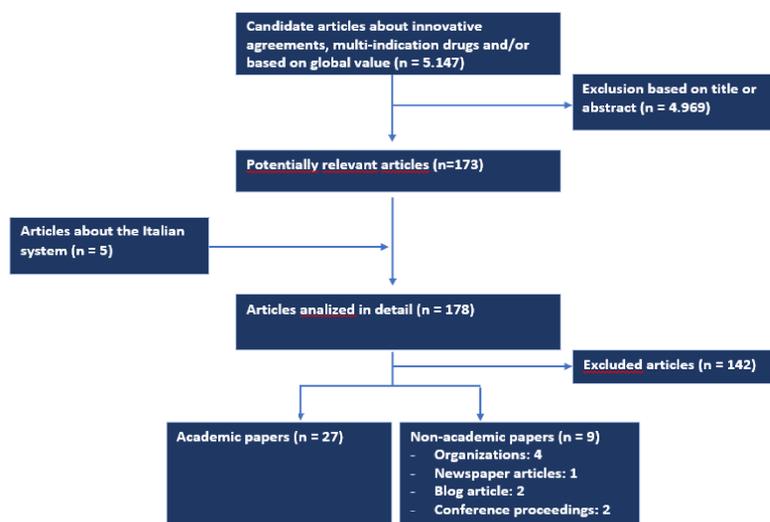
Imposing a uniform price on a drug whose clinical value varies across indications is potentially harmful, as it misaligns social and industry incentives. We review the literature to investigate whether there exist indication-specific pricing models (ISP) that can align clinical value and price in each indication and evaluate their pros and cons.

METHODS

- We performed an extensive systematic literature review about multi-indication pricing models worldwide, both in grey and academic sources, including: Pubmed, EMA, ISPOR, financial reviews, press releases, Medicare, Medicaid, Veterans Health Administration, Google, Google Scholar, HMO and NICE and AIFA web pages. The retrieved papers were analyzed based on the year, country, type of agreement, its characteristics and the therapeutic area.
- We discuss the conditions that lead to the possibility of ISPs, types of ISPs, risks and benefits for payers and laboratories, the international experience and some examples of ISPs. We identified the obstacles for implementing the ISP and possible solutions. We analyzed the Italian case in detail, as Italy is the country with a higher experience in ISP implementation.

RESULTS

Fig. 3: Literature review



- The analysis showed that there are three types of ISPs: (i) different brand names for each indication, (ii) different discount for each indication, and (iii) a weighted average price, where the price reflects the benefit in each weighted indication by the population covered in each indication.
- Payers and society benefit from multi-indication pricing in that clinical value is aligned to price, fostering incentives of R&D where they are more needed, and minimize the risk of paying a high amount of money in low-value indications. The main cost is due to the administrative burden of keeping the information needed for multi-indication pricing.
- Laboratories benefit from multi-indication pricing in that they erase the risk of price reduction in case new indications are approved. The main downside for laboratories is the need to monitor that hospitals actually use the drug in the indications they pay for.
- The UK, Australia, and Italy have implemented, or have attempted to implement, some form of ISP. The country that most implemented them is Italy.

Country	ISP type	Details
	Single weighted average price	1) Manufacturers set the prices of medicines freely without regulatory intervention. 2) Pharmaceutical Benefits Advisory Committee (PBAC) calculates the cost-effectiveness and decides to approve or not. 3) Price negotiation of the indication occurs only at the weighting level, leading to a single weighted average price. Examples of drugs that have received an explicit weighted average price in PBS include Raltegravir for HIV treatment and Aprepitant as an antiemetic drug.
	ISP in one indication	1) The UK introduced an optional flexible pricing scheme in the Pharmaceutical Price Regulation Scheme of 2009 (PPRS). 2) Manufacturers are allowed a single price increase for a new indication (the price increase would not come into force until NICE had approved its use in the final guidance). 3) Only one price increase is possible and the company must provide the medicine at the old price for the original indication. 4) This flexible pricing scheme has not been used yet.
	ISP as different discounts	The manufacturer offers different indication-specific discounts. This mechanism is used for Avastin, for which only the low dose regimen is reimbursed in lung cancer.
	ISP as different discounts	1) Italy created, within its regulatory body (AIFA), registries of oncological and hematological medicines depending on their indication. 2) Registries, initially created for the "authorized off-label use", contain several variables, including indication, patient characteristics, dose, and duration. 3) If the hospital interrupts the treatment, it sends a reimbursement request to the laboratory. The laboratory reviews the request and (if it agrees) reimburses the hospital. Examples of drugs whose price depends on the indication are Avastin® (Bevacizumab), Cimzia® (Certolizumab pegol), Erbitux® (Cetuximab) and Afinitor® (Everolimus).

CONCLUSIONS

Indication-specific pricing is a novel tool in many countries, though Italy already implemented it quite widely. More drugs have multiple indications, so aligning price and value will become more compelling in the next future. We show that their implementation is feasible and no major hurdle impedes it in Spain.

REFERENCES

- [1] Aitken M., Blansett, L. and Mawrie, R., 2015. *Developments in cancer treatments, market dynamics, patient access and value*. Global Oncology Trend Report 2015. The IMS Institute for Healthcare Informatics. Parsippany, NJ: IMS Health. [2] Australian Government Department of Health. PBAC Guidelines Version 4.4. <http://www.pbac.pbs.gov.au/information/rationale-and-basis-for-economic-evaluation.html>. Accessed November 23, 2015. [3] Bach, P., 2014. *Indication-specific pricing for cancer drugs*. Journal of the American Medical Association, 312(16), pp.1629–1630. [4] Chapman, A. and Karslberg Schaffer, S., 2015. *Assessing the use of multi-indication medicines: a review of current data capabilities in the UK*. OHE Consulting Report, London. [5] Flume M., Bardou M., Capri S., Sola-Morales O., Cunningham D., Levin L.A., Touchot N. (2016), *Feasibility and Attractiveness of Indication Value-based Pricing in key EU countries*, Journal of Market Access and Health Policy, Vol.4. [6] Mestre-Ferrandiz J, Towse A, Dellamano R, Pistollato M. Multi-indication pricing: *Pros, cons, and applicability to the UK*. 2015. [7] Montilla S., Xoxi E., Russo P., Cicchetti A., Pani L. (2015), *Monitoring Registries at Italian Medicines Agency: Fostering Access, Guaranteeing Sustainability*. Int. J. Technology Assessment in Health Care, Vol.31, p.210-213. [8] Paris V, Belloni A. *Value in Pharmaceutical Pricing. Country Profile: Australia*. Organisation for Economic Co-operation and Development (OECD); November 2014. [9] Pearson S.D., Dreitlein B., and Henshall C. (2016), *Indication-specific pricing of pharmaceuticals in the United States Health Care System*, Report from the 2015 ICER Membership Policy Summit.